

## REMARKS

### Status of the Claims

Claims 1-12 are pending. Claims 2, 3, and 7-12 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention.

Claims 1 and 4-6 are currently under consideration. Claim 1 has been amended herein to more particularly point out the invention. Support for the amendments is found in the specification on page 13, lines 29-36, page 22, lines 30-36.

New claims 13-19 have been added to more particularly point out the invention. Support for these claims is found in the specification on page 18, lines 6-15 and 25-27; and page 19, lines 1-17. No new matter has been added.

Applicants gratefully acknowledge the withdrawal of the rejections under 35 U.S.C. § 112 first and second paragraphs. Applicants also thank the Examiner for the interview granted on June 8, 2004.

### Enablement Rejection Under 35 U.S.C. § 112

Claims 1 and 4-6 stand rejected under 35 U.S.C. § 112 first paragraph as allegedly not enabled by the specification. The Office alleges that there is no evidence of record that the combination of gene therapy and enzyme replacement therapy using  $\alpha$ -galactosidase A provide sufficient quantities of the enzyme at target cells in vivo to ameliorate the symptoms of Fabry disease in a patient. The Office further alleges that the claims are not enabled because the specification fails to provide adequate guidance and evidence regarding how to use any vector expressing any lysosomal hydrolase, including  $\alpha$ -galactosidase A, for gene therapy in combination with any lysosomal

hydrolase protein for enzyme replacement therapy. The Office concludes it would require undue experimentation for one skilled in the art to practice the full scope of the claimed invention. Without conceding the correctness of the rejection, Applicants have amended claim 1 herein. Applicants believe this amendment obviates the enablement rejection.

**CONCLUSION**

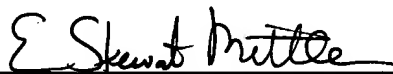
In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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